K103771

510(k) Summary

MAY - 6 2011

Letrix Power Hangzhou Pty Ltd.

Esteem scooter

Sponsor and proprietary--manufacturer information

Manufacturer:
Letrix Power Hangzhou Pty Ltd.
NO.225, CHUTIAN ROAD BINJIANG DISTRICTS, HANGZHOU CHINA
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Sponsor:
Robert Dunn
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Device

Trade Name: LotusBlake Esteem
Common name: Electrical invalid scooter
Classification name: Motorized 3-wheeled vehicle
Medical specialty (Panel): Physical Medicine Device
Regulation number: 890.3800
Product Code: INI
Classification: Class 2

Predicate Device

Manufacture name: Pride Mobility Products Corp
Name: Victory 4 wheel scooter Model SC610
K number: K071949
Date cleared: August 1st 2007

Intend use of device

Esteem scooter is intended for an indoor/outdoor scooter that provides transportation for disabled or elderly person limited to a seated position.

Device description:

The Esteem invalid scooter is motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly person limited to a seated position.

The Esteem invalid scooter consist of a chassis, shroud, transaxle, seat, controller, batteries, and battery charger. It also includes a tiller handle for steering and a thumb or finger operated potentiometer throttle control level to engage and disengage the scooter motion in both the forward and reverse directions.

The scooter is powered by two 12 volt 28ah sealed lead-acid (AGM or Gel type) batteries with 19 miles range. The maximum speed is up to 6mph. The rigid chassis features an advanced design that has a superior static weight distribution resulting in dynamic performance that greatly improves safety and ride comfort

Chassis:

Abstract: The advanced chassis has 4 wheel suspension and the batteries are mounted low and at the front to create the ideal 50:50 static weight distribution and lower the centre of gravity thereby providing greater safety and improving the ride and steering characteristics of the scooter.

There is a battery tray area near the front of chassis. Ahead of this are mounts for the front upper and lower suspension arms.

The front upper and lower suspension arms are shaped in such a way as to come around the battery tray area and back along the battery tray area so that the stub axles are behind the line of the front edge of the batteries. The joining of the front and rear chassis pieces is automatic, electrically and mechanically, allowing easy separation of the two parts of the scooter for easy transport and storage. The rear chassis with independent rear suspension provides greater resistance to sideways tipping and provides superior traction and ride comfort.

Seat and seat base:
The seat base sits on four seat posts providing great stability. The two armrests are adjustable for width and height to suit different size persons. Armrests can be raised up and out of the users way to allow easy access. The seat can be also swiveled for easy access. The seat height is also adjustable. The seat can also be adjusted forward and back on a sliding base. The back rest can be inclined as required. The seat has molded foam over 4 seat springs for improved comfort. The seat material is automotive vinyl for durability and ease of cleaning.

Shroud:
The body shroud is 1st grade ABS plastic coated with automotive 2 pack epoxy paint finish in a variety of colors.

Lights:
The lights meet with EUR road regulations. There is a front headlight mounted 550mm above the ground and two front indicators, there are two rear stop lights and two rear indicators and two rear reflectors in red.

Transaxle and brake
A DC electric motor supplies power to the scooter through a three stage gear reduction, differential assembly and drive shafts to both rear wheels. An electro magnetic brake is attached to the transaxle drive shaft to provide positive braking. The braking function is applied when no electric current passes its inductive coils and vanishes when the speed control throttle is activated. The scooter will stay firmly on a slope of greater than 15degrees without slipping. There is a brake release lever located under the rear that can be manually operated only when off the scooter should the user have the need to manually push the scooter. An inhibit switch and control prevent the scooter from being ridden whilst the brake is disengaged

Batteries:
There are two Panasonic deep cycle SLA (AGM) 28ah 12-volt deep cycle rechargeable batteries usually supplied with the scooter. These batteries are designed for and are ideal for this application and are proven to provide long range and long life. Other batteries of similar specification may also be fitted as replacement parts with no adverse effect.

Electronic control and dash panel:
The speed of the scooter is controlled by an electronic control system. The maximum speed of the Esteem is 6 miles per hour . The scooter uses the Curtis PMC controller American Tech, made in China, that is widely used in powered invalid scooters all over the world. There is HPD feature which prevents the scooter from driving should the user turn on the key whilst unknowingly operated the throttle. This controller is the most advanced known to us and incorporates many safety and operational overrides, regardless of operator input. It also features many self diagnosis features and has proven durable and is very reliable in service. It meets all EMI requirements. (see attachment) The modern dash console has a battery indicator to show the state of battery energy, a potentiometer to set desired maximum speed, a high and low power switch, two easily accessible horn buttons, a headlight switch and toggle switch for right and left turning indicators. A LCD display has a speedometer, odometer and trip meter greatly enhancing the users experience and providing data for servicing.

Freewheel:
A lever under the rear of the scooter can be pulled down to release the electro magnetic brake to allow the scooter to be pushed. The controller can sense this and will not allow the user to ride the scooter with the brake released. Further the controller can sense the speed at which the scooter is moving when the brake is released and this is regulated to a maximum speed of 3mph thus preventing possible overrun down a steep slope. Also the lever is designed in such a way as to prevent accidental release should the rider drive over an unusual obstacle.

Specifications:

Scooter weight:	175 pounds
Max. Power:	350watt
Length:	47.5 inches
Width:	25 inches
Wheelbase:	36.5 inches

Turning circle	9 ft 6 inches
Climb angle	20 degree
Max. Speed:	6 mph
Range:	19 miles

Substantial equivalence:
The Esteem scooter has the same intended use and similiar technology characteristics as the Victory 4 wheel scooter. K071949 The non clinical testing and the predicate comparisons show that the differences in design and technologies do not raise any new questions of safety or effectiveness. Moreover the variations in design in fact lead to the Esteem scooter being a safer and more stable scooter. The Esteem scooter is substantially equivalent to the predivate device. The Esteem scooter has passed all testing requirements and is considered to be safe for the user to operate. Furthermore the Esteem scooter has been in the Australian market since 2003 with no adverse outcomes or safety related isssues having been detected.

Special Controls
Non-Clinical test
According to **ESSENTIAL REQUIREMENTS of COUNCIL DIRECTIVE MDD93/42/EEC of 14 June 1993** concerning medical devices. Esteem invalid scooter has been tested to wheelchair standard and approvals, They include:

1. ISO7176-1:1999 Wheelchairs-Part 1: Determination of Static Stability
2. ISO7176-2:2001 Wheelchairs-Part 2: Determination of Dynamic Stability of Electric wheelchairs.
3. ISO7176-3:2003 Wheelchairs-Part 3: Determination of Efficiency of Brakes.
4. ISO7176-4:2008 Wheelchairs-Part 4: Energy Consumption of Electric Wheelchairs and Scooter for Determination theoretical distance and or range.
5. ISO7176-5:2008 Wheelchairs-Part 5: Determination of Overall Dimensions, Mass, and turning Space.
6. ISO7176-6:2001 Wheelchairs-Part 6: Determination of Maximum Speed, Acceleration of Electric Wheelchairs.
7. ISO7176-9:2001 Wheelchairs-Part 9: Climatic Tests for Electric Wheelchairs.
8. ISO7176-10:2008 Wheelchairs-Part 10: Determination of Obstacle-Climbing Ability of Electric Wheelchairs.
9. ISO7176-11:1992 Wheelchairs-Part 11: Test Dummies
10. ISO7176-13:1989 Wheelchairs-Part 13: Determination of Coefficient of Friction of Test Surfaces.
11. ISO7176-14:2008 Wheelchairs-Part 14: Power and Control Systems for Electric Wheelchairs Requirements and test Methods.
12. ISO7176-15:1996 Wheelchairs-Part 15: Requirements for Information Disclosure, Documentation and Labeling.
13. ISO7176-16:1997 Wheelchairs-Part 16: Resistance to Ignition of Upholstered Parts-Requirements and Test Methods.
14. ISO7176-21-2009 Wheelchairs-Part 21Requirements and test methods for electromagnetic compatibility of electrically powered wheel chairs and scooters and battery chargers

The performance data for the Esteem invalid scooter is presented in Chapter 4--Quality Control Measures and Packaging, labeling.

Quality system
The Esteem scooter has been covered by Manufacturer quality system, according to 21CFR820.

1. Education and Training --Meeting 21CFR820.25
Letrix Power engages in regular and ongoing employee training regardless of qualification or previous experience. Experienced employees with ability over time become group leaders with at least one experienced assistant in each group. New and less experienced employees are buddied with more experienced employees who are then overseen by the group leaders and assistants. In fact the workforce is and has remained very stable over many years with most employees having 5 or more years experience. Weekly sessions are held to discuss ideas for improvement of production process, with a strong bias on how to always improve quality output. The Quality control department leaders have authority to implement extra training sessions and possible disciplinary action should sub standard processes be detected. Every defect found in the field by the end users is catalogued by serial number back to the actual production group and possibly the individual worker. Each worker through a bonus scheme and sometimes disciplinary action is vigorously encouraged to be responsible for and take pride in their workmanship and output. Modern (Australian) standards of training, workmanship, behavior, health and safety are applied throughout.

2. Document control –Meets or exceeds 21CFR820.40
Letrix Power has a well established set of procedures and forms in place to accurately document and analyze all areas and items of production input and output. See. Annex 1 Form-1/Form-2/Form-3/Form-4/Form-5

All forms are catalogued and can be reviewed or exchanged by each department in Letrix Power Hangzhou Pty Ltd.
PUR. Department; Purchasing Department
IQC. Department; Import Quality Control Department
QC. Department; Quality Control Department
QA. Department; Quality Assurance Department
PE. Department; Production Engineering Department
PRO. Department; Production Department
PD. Department; Production Design Department
MS. Department; Material Storage
FPS. Department; Finish Production Storage

3. **Purchase Control--Meets or exceeds 21CFR820.50** see; Annex 2 **Flow Chart-1 /Form-1/Purchase Contract.**

4. **Production and Process Controls –Meets or exceeds 21CFR820.70/72/75..** See; Annex 3 The Flow Chart 2--6. clearly shows that the Esteem scooter is produced under the control of and in line with 21CFR820.

5. **Labeling and Packing control-Meets or exceeds 21CFR820.120 and 21CFR-820.130** High quality plastic labels for use instructions and warnings are affixed to the product. Each label is easy to read, correctly positioned, and informative. Each label is UV and water resistant and will remain legible for the expected life of the product. Each product is packaged in large strong cardboard boxes with internal struts and segments and insulation to provide robust protection in transportation and distribution that can protect the product against damage even if abused during transportation (within reasonable limits)

6. **Handling, storage, distribution meets or exceeds 21CFR820.140/150/160** Each separate product is clearly labeled in words, numbers, bar code and by color coding and stored in its designated area prior to shipping. Lowest numbered products are shipped first ensuring proper stock rotation. Manual and electronic picking records from different sources are matched against barcodes at the time of shipping to ensure the correct product is and will be shipped

7. **Installation meets or exceeds 21CFR820.170** No installation is required. Each product is shipped ready for use in 1 large carton.

8. **Records meets or exceeds 21CFR820.180 21CFR820.181 21CFR820.184 21CFR820.186** Records required by these parts and additional records are stored in document form in fireproof cabinets for a period of not less than 7 years. Electronic records from a variety of sources are backed up regularly and stored on external discs and drives in a fireproof cabinet off site.

9. **Complaint Files meets or exceeds 21CFR820.198** Records are received and maintained in line with this procedure. The manufacturers address and or website appears on the product and packaging. All dealers, service agents and distributors are required to register each and every complaint or defect with the manufacturer. Usually by email with photographic evidence. The end user has the ability to contact the manufacturer direct with each complaint. Matching of data quickly by the manufacturer allows any potential issue of quality, production or design to be assessed and addressed immediately.

10. **Servicing meets or exceeds 21CFR820.200** The manufacturer supplies the product with a users service manual suggesting a yearly service schedule. Each distributor or dealer is assisted by the manufacturer in acquiring the correct tooling and techniques to undertake regular service and repairs on product in the field.

11. **EMI**

Intertek testing laboratories EMC test report no. SH10071042-001 September 15th 2010 Attached
test Specification ISO7176-21: 2009
Curtis Controller model 1228
Curtis PMC 6591 SierraLn Dublin CA 94568
Testing laboratory Intertek Testing Services 1365 Adams Court Menlo Park CA 94025
Test specification IEC 60 601-1-4:96

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Letrix Power Hangzhou Pty Ltd.
% Mr. Robert Dunn
10352 Stanford Road
Garden Grove, California 92840

MAY - 6 2011

Re: K103771
Trade/Device Name: Lotus Blake Esteem
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: Class II
Product Code: INI
Dated: April 8, 2011
Received: April 13, 2011

Dear Mr. Dunn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

Proprietary Name:	Lotus Blake Esteem
Common Name:	Electrical Invalid Scooter
Classification Name:	Motorized 3 wheeled vehicle
Product Code:	INI 890.3800 Class 2

Indications For Use:

Esteem scooter is intended for an indoor/outdoor scooter that provides transportation for disabled or elderly person limited to a seated position.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Page 1

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103771